

In the Claims:

1. (currently amended) A process for producing a ~~film-shaped~~ preparation for administration of substances to the human or animal body, said preparation being in the form of a film or of a wafer, being disintegratable in aqueous media and containing at least one water-soluble polymer and at least one gas-forming component which produces a gas upon action of moisture, being in the presence of an aqueous medium or by a temperature change, comprising the steps of:

preparing a coating compound which contains the components of the preparation including said at least one gas-forming component by dissolving or suspending the components in a solvent or suspending agent that is substantially free from water;

spreading said coating compound on a support; and

drying said support coating compound.

2. (previously presented) The process according to claim 1, wherein said at least one gas-forming component is selected from the group consisting of carbonates, acids and acid regulators.

3. (previously presented) The process according to claim 2, wherein said at least one gas-forming component is a combination of at least one first component and at least one second component, wherein said at least one first component is a carboxylic acid, and said at least one second component is selected from the group consisting of sodium hydrogen carbonate, sodium carbonate, potassium carbonate and potassium hydrogen carbonate.

4. (previously presented) The process according to claim 1, further comprising the step of the adding at least one pharmaceutical active substance to said preparation.

5. (previously presented) The process according to claim 1, further comprising the step of adding a flavouring agent to said preparation.

6. (currently amended) A ~~film-shaped~~ preparation disintegratable in aqueous media, for administration of substances to the human or animal body, containing at least one water-soluble polymer, said preparation being in the form of a film or of a wafer and containing at least one gas-forming component two or more gas-forming components which are homogenously distributed within the preparation, said components being able to produce a gas upon action of moisture, being in the presence of an aqueous medium or by a temperature change.

7. (withdrawn) A film-shaped preparation disintegratable in aqueous media, for administration of substances to the human or animal body, containing at least one water-soluble polymer, said preparation containing at least one gas-forming component able to produce a gas upon action of moisture, being in the presence of an aqueous medium or by a temperature change, wherein at least one of said at least one gas-forming component is in a microencapsulated form.

8. (withdrawn) A film-shaped preparation disintegratable in aqueous media, for administration of substances to the human or animal body, containing at least one water-soluble polymer, said preparation containing at least one gas-forming component able to produce a gas upon action of moisture, being in the presence of an aqueous medium or by a temperature change, wherein said preparation has two film layers connected to each

other, the first film layer containing a first gas-forming component and further components of the film-shaped preparation, and the second film layer containing a second gas-forming component and further components of the film-shaped preparation, wherein said first and second gas-forming components are reaction partners of a gas-forming reaction.

9. (withdrawn) The preparation according to claim 7, wherein said at least one gas-forming component is selected from the group consisting of carbonates, acids and acid regulators.

10. (withdrawn) The preparation according to claim 9, wherein said gas-forming components comprise a combination of at least one first component and at least one second component, wherein said at least one first component is a carboxylic acid, and said at least one second component is selected from the group consisting of sodium hydrogen carbonate, sodium carbonate, potassium carbonate and potassium hydrogen carbonate.

11. (previously presented) The preparation according to claim 6, wherein said preparation produces CO₂ or N₂ under action of water, an aqueous medium or moisture.

12. (previously presented) The preparation according to claim 6, wherein said preparation produces an acid environment in the presence of water.

13. (currently amended) The preparation according to claim 6, wherein said preparation disintegrates in the presence of water or an aqueous medium within 1 [[s]] second to 5 [[min]] minutes.

14. (previously presented) The preparation according to claim 6, wherein said preparation

is swellable in aqueous media.

15. (previously presented) The preparation according to claim 6, wherein said preparation further contains at least one pharmaceutical active substance.

16. (previously presented) The preparation according to claim 6, wherein said preparation further contains a flavouring agent.

17. (previously presented) The preparation according to claim 6, wherein said preparation comprises at least two layers.

18. (previously presented) The preparation according to claim 6, wherein said preparation has a thickness between 5 μm and 3 mm.

19. (previously presented) The preparation according to claim 6, wherein said preparation is an administration form selected from the group consisting of an oral administrative form, a rectal administrative form and a vaginal administrative form for administration of pharmaceutical active agents.

20. (previously presented) The process according to claim 2, wherein said carbonates are selected from the group consisting of sodium carbonate, ammonium carbonate, magnesium carbonate, potassium carbonate, and hydrogen carbonate, said acids are selected from the group consisting of citric acid, malic acid, acetic acid, lactic acid, fumaric acid, gluconic acid and tartaric acid, and said acid regulators are selected from the group consisting of salts of acetic acid, sodium dihydrogen phosphate, disodium hydrogen phosphate, sodium tartrate and sodium ascorbate.

21. (previously presented) The process according to claim 20, wherein said hydrogen carbonate is sodium hydrogen carbonate.

22. (previously presented) The process according to claim 3, wherein said carboxylic acid is selected from the group consisting of citric acid, malic acid, acetic acid, lactic acid, fumaric acid, gluconic acid and tartaric acid.

23. (previously presented) The process according to claim 5, wherein said flavouring agent is menthol.

24. (withdrawn) A process for producing a film-shaped preparation for administration of substances to the human or animal body, said preparation being disintegratable in aqueous media and containing at least one water-soluble polymer and at least one gas-forming component which produces a gas upon action of moisture, being in the presence of an aqueous medium or by a temperature change, comprising the steps of:

preparing a first coating compound which contains a first gas-forming component and further components of the film-forming preparation by dissolving or suspending said components in an aqueous solvent or suspending agent;

preparing a second coating compound which contains said first gas-forming component and further components of the film-shaped preparation by dissolving or suspending said components in an aqueous solvent or suspending agent, said first and said second components being reaction partners of a gas-forming reaction;

spreading the first coating compound on a support;

drying said support to form a first film;

spreading the second coating compound on a support;

drying said support to form a second film; and

laminating said first film and said second film onto each other.

25. (withdrawn) The process according to claim 24, wherein said at least one gas-forming component is selected from the group consisting of carbonates, acids and acid regulators.

26. (withdrawn) The process according to claim 25, wherein said carbonates are selected from the group consisting of sodium carbonate, ammonium carbonate, magnesium carbonate, potassium carbonate, and hydrogen carbonate, said acids are selected from the group consisting of citric acid, malic acid, acetic acid, lactic acid, fumaric acid, gluconic acid and tartaric acid, and said acid regulators are selected from the group consisting of salts of acetic acid, sodium dihydrogen phosphate, disodium hydrogen phosphate, sodium tartrate and sodium ascorbate.

27. (withdrawn) The process according to claim 26, wherein said hydrogen carbonate is sodium hydrogen carbonate.

28. (withdrawn) The process according to claim 24, wherein said at least one gas-forming component is a combination of at least one first component and at least one second component, wherein said at least one first component is a carboxylic acid, and said at least one second component is selected from the group consisting of sodium hydrogen carbonate, sodium carbonate, potassium carbonate and potassium hydrogen carbonate.

29. (withdrawn) The process according to claim 28, wherein said carboxylic acid is selected from the group consisting of citric acid, malic acid, acetic acid, lactic acid, fumaric acid, gluconic acid and tartaric acid.

30. (withdrawn) The process according to claim 24, further comprising the step of the adding at least one pharmaceutical active substance to said preparation.

31. (withdrawn) The process according to claim 24, further comprising the step of adding a flavouring agent to said preparation.

32. (withdrawn) The process according to claim 31, wherein said flavouring agent is menthol.

33. (withdrawn) A process for producing a film-shaped preparation for administration of substances to the human or animal body, said preparation being disintegratable in aqueous media and containing at least one water-soluble polymer and at least one gas-forming component which produces a gas upon action of moisture, being in the presence of an aqueous medium or by a temperature change, or comprising the steps of:

preparing a coating compound which contains the components of the preparation including said at least one gas-forming component by dissolving or suspending the components in a solvent or a suspending agent, wherein at least one of said at least one gas-forming component is present in a microencapsulated form;

spreading said coating compound on a support; and
drying said support.

34. (withdrawn) The process according to claim 33, wherein said at least one gas-forming component is selected from the group consisting of carbonates, acids and acid regulators.

35. (withdrawn) The process according to claim 34, wherein said carbonates are selected from the group consisting of sodium carbonate, ammonium carbonate, magnesium carbonate, potassium carbonate, and hydrogen carbonate, said acids are selected from the group consisting of citric acid, malic acid, acetic acid, lactic acid, fumaric acid, gluconic

acid and tartaric acid, and said acid regulators are selected from the group consisting of salts of acetic acid, sodium dihydrogen phosphate, disodium hydrogen phosphate, sodium tartrate and sodium ascorbate.

36. (withdrawn) The process according to claim 35, wherein said hydrogen carbonate is sodium hydrogen carbonate.

37. (withdrawn) The process according to claim 33, wherein said at least one gas-forming component is a combination of at least one first component and at least one second component, wherein said at least one first component is a carboxylic acid, and said at least one second component is selected from the group consisting of sodium hydrogen carbonate, sodium carbonate, potassium carbonate and potassium hydrogen carbonate.

38. (withdrawn) The process according to claim 37, wherein said carboxylic acid is selected from the group consisting of citric acid, malic acid, acetic acid, lactic acid, fumaric acid, gluconic acid and tartaric acid.

39. (withdrawn) The process according to claim 33, further comprising the step of the adding at least one pharmaceutical active substance to said preparation.

40. (withdrawn) The process according to claim 33, further comprising the step of adding a flavouring agent to said preparation.

41. (withdrawn) The process according to claim 40, wherein said flavouring agent is menthol.

42. (currently amended) The preparation according to claim 13, wherein said preparation disintegrates in the presence of water or an aqueous medium within 1 [[s]] second to 1 [[min]] minute.

43. (currently amended) The preparation according to claim 42, wherein said preparation disintegrates in the presence of water or an aqueous medium within 1 [[s]] second to 30 [[s]] seconds.

44. (previously presented) The preparation according to claim 16, wherein said flavouring agent is menthol.

45. (previously presented) The preparation according to claim 18, wherein said preparation has a thickness between 10 µm and 1 mm.

46. (previously presented) The preparation according to claim 45, wherein said preparation has a thickness 20 µm and 500 µm.

47. (withdrawn) The preparation according to claim 9, wherein said carbonates are selected from the group consisting of sodium carbonate, ammonium carbonate, magnesium carbonate, potassium carbonate, and hydrogen carbonate, said acids are selected from the group consisting of citric acid, malic acid, acetic acid, lactic acid, fumaric acid, gluconic acid and tartaric acid, and said acid regulators are selected from the group consisting of salts of acetic acid, sodium dihydrogen phosphate, disodium hydrogen phosphate, sodium tartrate and sodium ascorbate.

48. (withdrawn) The preparation according to claim 47, wherein said hydrogen carbonate is sodium hydrogen carbonate.

49. (withdrawn) The preparation according to claim 10, wherein said carboxylic acid is selected from the group consisting of citric acid, malic acid, acetic acid, lactic acid, fumaric acid, gluconic acid and tartaric acid.

50. (withdrawn) The preparation according to claim 7, wherein said preparation produces

CO₂ or N₂ under action of water, an aqueous medium or moisture.

51. (withdrawn) The preparation according to claim 7, wherein said preparation produces an acid environment in the presence of water.

52. (withdrawn) The preparation according to claim 7, wherein said preparation disintegrates in the presence of water or an aqueous medium within 1 s to 5 min.

53. (withdrawn) The preparation according to claim 52, wherein said preparation disintegrates in the presence of water or an aqueous medium within 1 s to 1 min.

54. (withdrawn) The preparation according to claim 53, wherein said preparation disintegrates in the presence of water or an aqueous medium within 1 s to 30 s.

55. (withdrawn) The preparation according to claim 7, wherein said preparation is swellable in aqueous media.

56. (withdrawn) The preparation according to claim 7, wherein said preparation further contains at least one pharmaceutical active substance.

57. (withdrawn) The preparation according to claim 7, wherein said preparation further contains a flavouring agent.

58. (withdrawn) The preparation according to claim 57, wherein said flavouring agent is menthol.

59. (withdrawn) The preparation according to claim 7, wherein said preparation comprises at least two layers.

60. (withdrawn) The preparation according to claim 7, wherein said preparation has a thickness between 5 µm and 3 mm.

61. (withdrawn) The preparation according to claim 60, wherein said preparation has a

thickness between 10 μm and 1 mm.

62. (withdrawn) The preparation according to claim 61, wherein said preparation has a thickness between 20 μm and 500 μm .

63. (withdrawn) The preparation according to claim 7, wherein said preparation is an administration form selected from the group consisting of an oral administrative form, a rectal administrative form and a vaginal administrative form for administration of pharmaceutical active agents.

64. (withdrawn) The preparation according to claim 8, wherein said at least one gas-forming component is selected from the group consisting of carbonates, acids and acid regulators.

65. (withdrawn) The preparation according to claim 64, wherein said carbonates are selected from the group consisting of sodium carbonate, ammonium carbonate, magnesium carbonate, potassium carbonate, and hydrogen carbonate, said acids are selected from the group consisting of citric acid, malic acid, acetic acid, lactic acid, fumaric acid, gluconic acid and tartaric acid, and said acid regulators are selected from the group consisting of salts of acetic acid, sodium dihydrogen phosphate, disodium hydrogen phosphate, sodium tartrate and sodium ascorbate.

66. (withdrawn) The preparation according to claim 65, wherein said hydrogen carbonate is sodium hydrogen carbonate.

67. (withdrawn) The preparation according to claim 64, wherein said gas-forming components comprise a combination of at least one first component and at least one second component, wherein said at least one first component is a carboxylic acid, and

said at least one second component is selected from the group consisting of sodium hydrogen carbonate, sodium carbonate, potassium carbonate and potassium hydrogen carbonate.

68. (withdrawn) The preparation according to claim 67, wherein said carboxylic acid is selected from the group consisting of citric acid, malic acid, acetic acid, lactic acid, fumaric acid, gluconic acid and tartaric acid.

69. (withdrawn) The preparation according to claim 8, wherein said preparation produces CO₂ or N₂ under action of water, an aqueous medium or moisture.

70. (withdrawn) The preparation according to claim 8, wherein said preparation produces an acid environment in the presence of water.

71. (withdrawn) The preparation according to claim 8, wherein said preparation disintegrates in the presence of water or an aqueous medium within 1 s to 5 min.

72. (withdrawn) The preparation according to claim 71, wherein said preparation disintegrates in the presence of water or an aqueous medium within 1 s to 1 min.

73. (withdrawn) The preparation according to claim 72, wherein said preparation disintegrates in the presence of water or an aqueous medium within 1 s to 30 s.

74. (withdrawn) The preparation according to claim 8, wherein said preparation is swellable in aqueous media.

75. (withdrawn) The preparation according to claim 8, wherein said preparation further contains at least one pharmaceutical active substance.

76. (withdrawn) The preparation according to claim 8, wherein said preparation further contains a flavouring agent.

77. (withdrawn) The preparation according to claim 76, wherein said flavouring agent is menthol.

78. (withdrawn) The preparation according to claim 8, wherein said preparation comprises at least two layers.

79. (withdrawn) The preparation according to claim 8, wherein said preparation has a thickness between 5 µm and 3 mm.

80. (withdrawn) The preparation according to claim 79, wherein said preparation has a thickness between 10 µm and 1 mm.

81. (withdrawn) The preparation according to claim 80, wherein said preparation has a thickness between 20 µm and 500 µm.

82. (withdrawn) The preparation according to claim 8, wherein said preparation is an administration form selected from the group consisting of an oral administrative form, a rectal administrative form and a vaginal administrative form for administration of pharmaceutical active agents.

83. (new) The process according to claim 1, wherein said polymer is selected from the group consisting of polyvinyl alcohol (PVA), polyethylene oxide, copolymer of methyl vinyl ether and maleic acid, cellulose derivatives such as hydroxypropyl methyl cellulose (HPMC), hydroxypropyl cellulose (HPC), sodium-carboxymethyl cellulose (NaCMC), methyl cellulose (MC), hydroxyethyl cellulose (HEC), hydroxypropyl ethyl cellulose (HPEC), starch and starch derivatives, gelatins, polyvinyl pyrrolidone (PVP), gum arabic, pullulan and acrylates.

84. (new) The process according to claim 1, wherein said polymer is selected from the group consisting of copolymer of methyl vinyl ether and maleic acid, pullulan and acrylates.

85. (new) The process according to claim 1, further comprising the step of adding one or more swellable substances.

86. (new). The process according to claim 85, wherein said swellable substances are selected from the group consisting of the hydrophile polyacrylates, hydrophile polymethacrylates, anionic or cationic hydrogels, agar, carboxymethyl cellulose, methyl cellulose, tragacanth, gelatine and swellable ion exchange resins.

87. (new) The preparation according to claim 6, wherein said polymer is selected from the group consisting of polyvinyl alcohol (PVA), polyethylene oxide, copolymer of methyl vinyl ether and maleic acid, cellulose derivatives such as hydroxypropyl methyl cellulose (HPMC), hydroxypropyl cellulose (HPC), sodium-carboxymethyl cellulose (NaCMC), methyl cellulose (MC), hydroxyethyl cellulose (HEC), hydroxypropyl ethyl cellulose (HPEC), starch and starch derivatives, gelatins, polyvinyl pyrrolidone (PVP), gum arabic, pullulan and acrylates.

88. (new) The preparation according to claim 6, wherein said polymer is selected from the group consisting of copolymer of methyl vinyl ether and maleic acid, pullulan and acrylates.

89. (new) The preparation according to claim 6, further comprising one or more swellable substances.

90. (new) The preparation according to claim 89, wherein said swellable substances are selected from the group consisting of the hydrophile polyacrylates, hydrophile polymethacrylates, anionic or cationic hydrogels, agar, carboxymethyl cellulose, methyl cellulose, tragacanth, gelatine and swellable ion exchange resins.